SPECIFICATION

Docket No. **0567MH-41654**

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN that we, **Michael A. Russell, Claude A. Vidal, Russell J. Redmond, David Chandos, Gilles Fitoussi** and **Menachem Zucker**, have invented new and useful improvements in an

ANESTHESIA MANIFOLD AND INDUCTION VALVE

of which the following is a specification:

BACKGROUND OF THE INVENTION

1. **Claim of Priority:** This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/417,422, filed 9 October 2002, entitled "Anesthesia Manifold"; and U.S. Provisional Patent Application Serial No. 60/401,019, filed 2 August 2002, entitled "Anesthesia Manifold." These provisional applications are incorporated herein as if fully set forth.

2. **Field of the Invention:**

This invention pertains to a novel valve and valve manifold to facilitate liquid anesthesia induction.

3. **Description of the Prior Art:**

Increasingly, anesthesiologists use liquid anesthetic agents, administered intravenously. This technique allows for faster anesthesia induction and faster corrective action if a patient shows sign of adverse reaction to the anesthesia. At the onset of the procedure, an IV catheter is inserted in a vein and connected to an IV bag providing a constant drip of saline via an IV line including one or, typically more, access sites for drug administration via syringes and/or IV pump.

Many such systems incorporate stopcocks, most frequently ganged together into a manifold configuration. While such devices function well, they require many handle manipulations. Such manipulations are not only tedious but they also can lead to errors. For instance, manipulating the handles of a stopcock manifold in the wrong way can result in the inadvertent dilution of a drug contained in a syringe attached to one of the ports.

Because of their need for a more user-friendly valve system, anesthesiologists have elected to use pressure or luer-activated valves because such valves are easier to use (one handed procedure and less risk of error). However pressure activated valves do

not allow for gravity infusions or for aspiration. Luer activated valves alone do not prevent retrograde flow when activated.

Thus, there is a growing need for better valves and valve manifolds for use in anesthesia. This disclosure describes a new concept, in light embodiments, aimed at facilitating anesthesia induction without the drawbacks of the existing valve systems.

SUMMARY OF THE INVENTION

The present invention is directed to an improved anesthesia manifold and an improved induction valve mechanism. A plurality of induction valve elements may be joined or "ganged" together in order to define a manifold. In the preferred embodiment of the induction manifold, at least two individual valve elements are combined to form the manifold. Each of the plurality of valve elements includes the following components: (1) a valve body; (2) a first inlet port carried by the valve body and defining at least in part a central fluid communication flow path for supplying intravenous fluid to a patient; and (3) a second inlet port carried said valve body and at least in part defining an anesthesia drug inlet. Each of the plurality of valve components include: (1) an induction valve mechanism which maintains said second inlet port in a closed condition until a predetermined amount of pressure is applied thereto; (2) a back flow valve mechanism which maintains said induction valve components in open condition to permit at least one of the following operations: (a) aspiration; (b) back flow; (c) purging; and (d) sampling.

Additionally, a control mechanism is provided for each of the plurality of individual valve components to actuate said induction valve mechanism and said backflow valve mechanism.

FIGURE DESCRIPTION

Figure 1 is a perspective, partial-phantom view of a valve member in its pressure-activated position.

Figure 2 is a one-quarter longitudinal section view of the induction valve of Figure 1.

Figure 3 is a detailed one-quarter longitudinal section view of the induction valve of Figures 1 and 2 in the pressure-actuated position which is suitable for both the gravity-fed flow mode of operation and the pressure-actuated flow mode of operation.

Figure 4 is a perspective and partial phantom view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Figure 5 is a partial one-quarter section view of the induction valve in the aspiration/backflow/purge/sample mode of operation.

Figure 5 is a partial one-quarter section view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Normal flow is shown by arrows 41, 43.

Figure 6 is a detailed one-quarter longitudinal section view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Normal flow and aspiration/purging flow are shown by arrows in this view.

THE FIRST EMBODIMENT:

Figures 7A and 7B depict the first embodiment of the anesthesia manifold of the present invention.

Figure 8 is a comparative side-by-side depiction of the first embodiment of the present invention with a prior art manifold.

Figures 9A, 9B and 9C are perspective and/or partial section views of the induction valve of the first embodiment of the present invention revealing the side passage.

Figures 10A and 10B are perspective views of the female luer and the seal of the first embodiment of the present invention.

Figure 11 is a perspective view of the valve in a pressure-activated position.

Figure 12 is a longitudinal section view of the induction valve of Figure 11 in the pressure activated position.

THE SECOND EMBODIMENT:

Figure 13 is a perspective view of the second embodiment of the anesthesia manifold valve of the present invention in an aspiration/backflow/purge/sample position.

Figure 14 is a longitudinal section view of the valve of Figure 13 in the aspiration/backflow/purge/sample position.

Figure 15 shows a number of the valve elements "ganged" together in order to form an anesthesia manifold which is composed of three separate valves each of which are individually actuable.

THE THIRD EMBODIMENT:

Figure 16 depicts a third embodiment of the present invention.

THE FOURTH EMBODIMENT:

Figure 17 depicts a fourth embodiment of the present invention.

THE FIFTH EMBODIMENT:

Figure 18 depicts the fifth embodiment of the present invention.

THE SIXTH EMBODIMENT:

Figure 19 is a depiction of the induction valve concept of the sixth embodiment in a pressure-activated position.

Figure 20 is a partial one-quarter longitudinal section view of the induction valve of the sixth embodiment in the pressure-activated position.

Figure 21 depicts the induction valve of the sixth embodiment in an aspiration/backflow/purge/sample mode of operation.

Figure 22 is a partial one-quarter longitudinal section view of the induction valve of the sixth embodiment in the aspiration/backflow/purge/sample mode of operation.

Figure 23 is a depiction of the induction valve of the sixth embodiment in a mode which allows aspiration from the main channel only.

Figure 24 is a one-quarter section view of the induction valve of Figure 23 in the

aspiration/backflow/purge/sample mode of operation which allows aspiration from the main channel only.

Figure 25 is a depiction of the induction valve of the sixth embodiment in the IV gravity feed mode of operation.

Figure 26 is a partial one-quarter longitudinal section view of the valve of Figure 25 in the IV gravity feed mode of operation.

Figure 27 depicts the induction valve of the sixth embodiment in a "ganged" assembly made up of three valves.

THE SEVENTH EMBODIMENT:

Figure 28 depicts the components which make up the seventh embodiment in exploded view form.

Figure 29 is a partial longitudinal section view of a portion of the seventh embodiment.

Figure 30 is a partial longitudinal section view of a portion of the seventh embodiment.

Figure 31 is a perspective view of the ring component 705 of Figure 28.

Figure 32 is a pictorial representation of a manifold formed with a number of the valves "ganged" together.

Figure 33 is a pictorial representation of an anti-rotational interlock feature.

5

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to an improved valve manifold for use in delivering liquid anesthesia. The invention also includes several alternative novel valve elements which can be "ganged" together to constitute a manifold. Six different embodiments are described in this application. All of them share common operational attributes. These attributes include: (1) the manifold is made up of a plurality of independently-operable valve elements; (2) each valve can be individually controlled and moved between any one of a plurality of predefined operating modes; (3) the two basic modes of operation include a pressure-activated flow mode of operation, and an aspiration/backflow/purge/sample mode of operation. This is true of all concepts except the one including luer activated valves (Fig. 18): for this manifold the two basic modes of operation include a luer-activated flow mode of operation and an aspiration/backflow/purge/sample mode of operation. This concept differs from the other members of this family; for instance it does not prevent retrograde flow when activated.

In operation, anesthesia drugs are administered through each individual valve of the valve manifold. The valve allows the anesthesia drug to mix into an IV line which receives a saline drip from an IV bag and delivers the mixture of saline fluid and the anesthesia drug to the patient intravenously through an IV catheter.

In the pressure-activated flow mode of operation, an individual valve is connected to a syringe which is utilized to push anesthesia drug through the individual valve into the IV line. Alternatively, it may be coupled to an IV pump. In this mode of operation, the valve is in a closed condition until a sufficient amount of pressure is applied to a pressure-responsive valve member. In this particular application, the actuation of the

syringe or the operation of the IV pump generates pressure sufficient to actuate the valve and allow the anesthesia drug to pass through the valve into the IV line. The valve element also operates to check or prevent retrograde flow through the valve.

In the aspiration/backflow/purge/sample mode of operation, an individual valve is utilized to withdraw fluids from the patient through the IV line, to allow aspiration of the valve and IV line, to purge the valve, or to obtain a blood sample. The aspiration/backflow/purge/sample mode of operation can be utilized to withdraw samples, typically utilizing a syringe.

In the following embodiments of the present invention, each individual valve member is described. All of them require that some component be moved in order to switch the valve between the modes of operation.

THE FIRST EMBODIMENT

The first embodiment of the present invention is depicted in Figures 1 through 10.

Figure 1 is a perspective, partial-phantom view of a valve member in its pressure-activated position. This position is suitable for both the gravity-fed flow mode of operation and a pressure-activated flow mode of operation. Figure 2 is a one-quarter longitudinal section view of the induction valve of Figure 1. In this view, the normal flow channel is defined by arrows 41, 43. Figure 3 is a detailed one-quarter longitudinal section view of the induction valve of Figures 1 and 2 in the pressure-actuated position which is suitable for both the gravity-fed flow mode of operation and the pressure-actuated flow mode of operation. Arrows are utilized to depict the normal flow through the valve.

Figure 4 is a perspective and partial phantom view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Figure 5 is a partial one-quarter section view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Normal flow is shown by arrows 41, 43. Figure 6 is a detailed one-quarter longitudinal section view of the induction valve in the aspiration/backflow/purge/sample mode of operation. Normal flow and aspiration/purging flow are shown by arrows in this view.

Figures 7A and 7B depict the first embodiment of the anesthesia manifold of the present invention. Figure 7A depicts the manifold with all of the individual valves set in a pressure-actuated position which allows either the gravity-fed flow mode of operation or the pressure-actuated flow mode of operation. In contrast, Figure 7B depicts the same induction valve of the first embodiment with each of the valve members in the aspiration/backflow/purge/sample mode of operation. Figure 8 is a comparative side-by-side depiction of the first embodiment of the present invention with a prior art manifold.

Figures 9A, 9B and 9C are perspective and/or partial section views of the induction valve of the first embodiment of the present invention revealing the side passage. Figures 10A and 10B are perspective views of the female luer and the seal of the first embodiment of the present invention.

Figures 1 through 10 will now be described in greater detail in order to illustrate the structure and function of the induction valve of the first embodiment of the present

invention. Turning first to Figure 1, a valve member 11 is depicted. The valve member 11 includes a female luer member 13 which is in-part disposed within valve housing 23 and in-part disposed above valve housing 23. The uppermost portion of female luer 13 includes integrally-formed external threads 15 which are adapted to engage with the internal threads of a male luer connector. Furthermore, the uppermost portion of female luer 13 includes a cavity 17 which is adapted to receive the male luer connector. Female luer 13 further includes integrally-formed wing members 19, 21 which are utilized to rotate female luer 13 relative to housing 23 in order to move between the two modes of operation. In the pressure-activated position the valve is suitable for the gravity-fed administration of anesthesia drugs through inlet port 33, the utilization of a syringe to administer anesthesia drugs through female luer member 13, and the use of an IV pump to administer anesthesia drugs also through female luer member 13. The female luer 13 may be rotated relative to housing 23 through use of thumb and forefinger to engage wing members 19, 21 and rotate the female luer between the positions depicted in Figures 1 and 4. As is shown in Figure 1, housing 23 includes a central cavity 25. Valve housing 23 includes integrally-formed inlet 27 and integrally-formed outlet 29. Inlet 27 includes integrally formed external threads 37 which are adapted to allow for the connection to an internally-threaded connector. An inlet port 33 is provided in order to allow the passage of fluid into valve housing 23. Exhaust port 31 is provided to allow the exit of fluid from valve housing 23.

In accordance with the preferred embodiment of the present invention, saline fluid from an IV line enters valve housing 23 at intake port 33, mixes with the anesthesia drugs, and exits from valve housing 23 at exhaust port 31. As the saline fluid passes through valve housing 23, anesthesia drugs are administered through cavity 17 of female luer 13. The flow of anesthesia drug is checked or stopped by seal 35 until a

sufficient amount of pressure is applied in order to flex a portion of seal 35 and allow the downward motion of fluid through the side flow channel 25 defined between valve housing 23 and the lower portion of female luer 13. The anesthesia drug will mix with the saline solution inside valve housing 23 and the mixture of saline solution and anesthesia drug will exit exhaust port 31 of valve housing 23 and flow toward the patient.

In the preferred implementation of the present invention, a plurality of valve members such as valve member 11 are "ganged" together in order to constitute a "manifold." Figure 7A depicts an anesthesia manifold which is composed of valve member 11 of Figure 1 and two additional valve members 83, 85. A review of Figure 7A depicts all three valve members 11, 83, 85 in the pressure-activated position which allows for the administration of three different anesthesia drugs (one through each of valves 11, 83, 85) into the manifold for mixing with the saline solution which passes first through valve 11, then to valve 83, and finally to valve 85. A lesser or greater number of valve elements may be ganged together if fewer or greater anesthesia drugs are to be administered.

Figure 2 is a one-quarter longitudinal section view of the valve member 11 of Figure 1. In this view, a portion of female luer 13, wing 21, and valve housing 23 are shown in one-quarter longitudinal section view. Flow arrow 41 and Flow arrow 43 show the normal flow of saline solution through valve member 11 in the pressure-activated mode of operation.

In the view of Figure 2, anesthesia drugs will pass downward through cavity 17 of female luer 13. The anesthesia drug will be under pressure due to the actuation of the

syringe plunger the valve must be such that it takes between 2 and 7 psi to open which precludes gravity feed and the use of IV pumps in this pressure activated mode; drugs can be added via gravity feed or IV pump when handles 19 and 21 are turned in the position shown on figure 4. If the user chooses to do so he/she may need to add a one-way valve in this secondary IV line, in order to eliminate the risk of drug dilution if the main IV line, connected to intake port 33 is set at a higher height or pressure. The anesthesia drug will pass through ports 51, 52, which are formed in female luer 13 one hundred and eighty degrees apart. Seal 35 is in contact with ports 51, 52 and will flex toward valve housing 23 when sufficient pressure is applied. Seal 35 also serves to check retrograde or backflow through ports 51, 52. The flexing of the seal will allow fluid to pass through the ports 51, 52 into a side flow channels 75, 76 which is defined between female luer 13 and valve housing 23.

Figure 3 graphically depicts this flow of pressurized anesthesia drug into the normal flowpath of the saline IV line. As is shown in Figure 3, flow arrows 61, 63, 65, 67, 69, and 71 show the progress of the anesthesia drug as it passes through cavity 17 of female luer 13, through ports 51, 52 and into contact with seal 35. As is shown in the view of Figure 3, seal 35 will flex toward valve housing 23 and permit the inward flow of anesthesia drug through side flow channels 75, 76. Side flow channels 75, 76 allow the anesthesia drug to pass into the central flow channel defined through valve housing 23. The anesthesia drug is then intermixed with the saline solution and passed toward the patient.

Figure 10A is a perspective of the preferred female luer of the first embodiment of the present invention. As is shown, female luer 13 includes three different types of ports, all which interconnect with cavity 17 which extends longitudinally downward through

female luer 13. Three different types of ports are provided. Upper ports 51, 52 (port 52 is not visible in this view) are utilized during the pressure-activated mode of operation. It allows pressurized anesthesia drugs to act against seal member 35 of Figure 10B in order to cause it to flex and thus permit the flow of the drug into the valve. Middle ports 53, 54 (port 54 is not visible in this view) are not utilized during the pressure-activated mode of operation. Instead, they are utilized during the aspiration/purge/backflow/sample mode of operation. A plurality of lower ports 55, 56, 57, 58 are provided at the lower portion of female luer 13. These are provided to allow the continuous flow of saline through female luer 13 and valve housing 23 during both modes of operation.

Turning to Figure 10B, seal 35 includes a radially-enlarged lip 79 which is utilized to secure seal 35 in position relative to valve housing 23. Note that seal member 35 is sufficiently long with respect to female luer 13 of Figure 10A to cover only the upper ports 51, 52 but not the middle ports 53, 54 or lower ports 55, 56, 57, 58.

Returning to Figure 10A, it is also important to note that upper ports 51, 52 and lower ports 53, 54 are located ninety degrees apart from one another so that rotation of female luer 13 by gripping wing members 19, 21 causes the alignment of upper port 51 with the side flow channel 75 during the pressure activated mode of operation, and upper port 52 with the side flow channel 76 and further allows the alignment of middle ports 53, 54 with the side flow channel 75 during the aspiration/backflow mode of operation.

Figures 4, 5 and 6 depict the first embodiment of the present invention in the aspiration/backflow/purge/sampling mode of operation. As is shown in Figure 4,

female luer 13 of valve 11 has been rotated ninety degrees relative to valve housing 23. In this configuration, wing members 19, 21 are in alignment with the flowparth defined by inlet 27 and outlet 29. Figure 5 is a partial one-quarter longitudinal section view of the valve of Figure 4. As is shown in this view, middle port 53 (of Figure 10A) is rotated to be adjacent side flow channel 75 which is defined between female luer 13 and valve housing 23. Upper port 51 is still sealed by seal member 35 which checks retrograde flow. Since middle port 53 provides no resistance to flow, valve 35 will not caused to flex outward and allow fluid to pass. In this configuration, there is an open flow path through port 53 between cavity 17 of female luer 13 and side flow channel 75. Fluid may be passed easily through middle port 53 to allow aspiration, purging, backflow and sampling. In the view of Figure 5, the normal flow channel is represented by in flow arrow 41 and out flow arrow 43.

Turning now to Figure 6, flow arrows 91, 93, 95, 97, 99, 101 are utilized to depict the potential for bi-directional movement of fluid through valve 11 when port 53 is aligned with side flow channel 75. In this configuration, fluid may be removed through valve 11 in order to take a sample. Additionally, the valve may be allowed to purge the manifold of a particular anesthesia drug. Additionally, the valve may be utilized to aspirate from the valve assembly. In the preferred embodiment, the valve of the present invention may be "ganged" together in order to provide a manifold. This is depicted in Figure 7B. In this view, valves 11, 103, 105 are all in the configuration which allows aspiration and/or backflow and/or purging.

Figures 9A, 9B, and 9C are perspective and section views of the valve housing 23 and are utilized to illustrate the location, size, and shape of the side flow channel 75 which is visible in Figures 2, 3, 5, and 6, as well as side flow channel 76 which is not

visible in those views. In the preferred implementation, the side flow channels 75, 76 are located one hundred and eighty degrees apart on the interior surface of valve housing 23. Valve housing 23 includes an annular recess 113 and lip 115 which are adapted in size and shape in order to engage radially enlarged lip 79 of seal 35 of Figure 10B. A recess region 131 is also provided which is adapted in size and shape in order to accommodate seal 35. The side flow channel 75, 76 extend downward therefrom and allow fluid communication with ports 118, 119 which are part of the normal flow main channel (which is illustrated by flow arrows 41, 43 in Figure 2 a circumferential rib 121 is provided at the lower end of valve housing 23 to engage with the groove provided at the lower end of 13 to allow retention of 13 into 23 via a snap-fit.

THE SECOND EMBODIMENT

The second embodiment of the anesthesia manifold of the present invention is depicted in Figures 11 through 15. Figure 11 is a perspective view of the valve in a pressure-activated position. Figure 12 is a longitudinal section view of the induction valve of Figure 11 in the pressure activated position. Figure 13 is a perspective view of the second embodiment of the anesthesia manifold valve of the present invention in an aspiration/backflow/purge/sample position. Figure 14 is a longitudinal section view of the valve of Figure 13 in the aspiration/backflow/purge/sample position. Figure 15 shows a number of the valve elements "ganged" together in order to form an anesthesia manifold which is composed of three separate valves each of which are individually actuable. The view of Figure 15 shows the manifold in the pressure-activated position.

With reference now to Figure 11, valve 211 is depicted in perspective and partial

phantom view. Valve 211 includes a valve housing 213 which communicates with inlet passage 215 and outlet passage 217. Furthermore, valve 211 includes a female luer 219 which includes integrally formed external threads 221 which are adapted to mate with corresponding internal threads from a male luer piece. Cavity 223 is provided in female luer connector. Cavity 223 communicates through port 251 to the normal central flow of saline from inlet 215, through valve body housing 213, and out through outlet 217. Valve 211 includes an elastomeric component 225 which includes a plug piece 227 and a "pigtail" member 231. In operation, the operator grabs and pulls the pigtail member 231 in order to move the valve between operating modes. An interconnecting member 229 and shoulder 235 are also provided. Preferably, the elastomeric member 225 is a unitary piece. It is located within channel 239 which includes a stop 239 at an upper, outer portion of inclined surface 237. Channel 239 is a guide way to allow the physical manipulation of the elastomeric member 225 between two positions. One position is shown in Figures 11 and 12. The other position is shown in Figures 13 and 14. In the position of Figures 11 and 12, the valve is in its pressure-activated mode of operation. In this particular configuration, anesthesia drugs are admitted through female luer 219. More particularly, the anesthesia drugs pass through cavity 223 of female luer 219 into passageway 251.

Turning now to Figure 12, the inflow of the anesthesia drugs will be pressurized through the actuation of the plunger of a syringe. The pressure is sufficient to act upon plug member 227 which is resident within cavity 261. The plug 227 is urged upward in order to allow the anesthesia drug to mix with the saline solution in the valve body 213. More particularly, side channels 263, 265 are provided which allow for the continuous flow of saline through valve housing 213. Only when the pressure of the anesthesia drug acting on plug member 227 is sufficiently strong, will the plug

member be moved upward and allow the ingress of anesthesia drugs.

As is shown in Figure 12, elastomeric member 225 extends through port 271 into cavity 261. The upper portion of plug member 227 serves to seal port 271. Connector member 229 includes a radially reduced portion 275 and a radially enlarged portion 277. Incline portion 237 includes an aperture 240 at its lower end. Shoulder 235 and the elasticity of elastomeric member 225 keep the plug member in a locked condition.

When the operator desires to aspirate, connect another IV line (with a one-way valve preventing dilution of the drugs dispensed through this line), sample, or purge the valve, he or she grabs the pigtail 231 and pulls upward and outward in order to allow radially reduced portion 271 of connector member 229 to move through channel 239. This is depicted in Figure 13, wherein pigtail member 231 has been moved from a position in which shoulder piece 235 is in engagement with the aperture 241. It has been moved from aperture 240 to aperture 241 through upward and outward movement. Figure 14 is a longitudinal section view which depicts the valve in aspiration backflow/purge/sample mode of operation. In this configuration, plug 227 has been pulled upward within cavity 261 of valve housing 13. This allows the three bi-directional flow of fluids between cavity 261, passageway 251, and cavity 223. This may be utilized to draw samples through a valve, or to connect another IV line (with a one-way valve preventing dilution of the drugs dispensed through this line), or to aspirate or purge the valve. Figure 15 is a pictorial representation of a plurality of a valves in accordance with second embodiment of the present invention "ganged" together in order to form a manifold. In this configuration, all valves are shown in the pressure-actuated position. In this configuration, anesthesia drugs will work against the plug and mix with the saline solution, provided that the pressure is sufficient to

"open" the valve to flow.

THE THIRD EMBODIMENT

Figure 16 depicts a third embodiment of the present invention. As is shown, anesthesia manifold is composed of individual valves 303, 305, 306 which are "ganged" together in order to form a manifold. As is shown, inlet 307 is provided to the manifold. The inlet receives saline solution from an IV line which is connected to an IV bag. The outlet 309 routes fluid to the patient. The anesthesia manifold 301 may be utilized to add anesthesia drugs to the saline solution prior to passage to the patient. Each of the valves 303, 305, 306 is individually actuable. Each may be utilized in the pressure-actuated mode in which a syringe is attached to female luer connector 311, 313, 315 to pass anesthesia drugs pressurized by the actuation of the syringe plunger into the valve for mixture with the saline solution. Each of valves 303, 305, 306 includes a rotatable handle 317, 319, 321. In the view of Figure 16, the valves 303, 305, 306 are shown with the handle rotated to a position which allows for aspiration of the line, connection of another IV line (with a one-way valve preventing dilution of the drugs dispensed through this line), backflow of fluid, or sampling of fluids. This configuration is depicted in partial section view in Figure 16 by valve 351. In this configuration, fluid may pass bidirectionaly through the female luer. Accordingly, the syringe may be utilized to purge, aspirate, or sample fluid from the valve. The longitudinal inset of valve 371 shows the valve in a pressure-actuated condition. Note that the handle is rotated ninety degrees from the position which is associated with backflow, aspiration, purging and sampling. In this configuration, a pressure-sensitive valve member is located in the flowpath of the female luer. When the pressure from the actuation of the syringe plunger is sufficient to overcome the valve element, anesthesia drugs may pass into the central flow line for mixture with

the anesthesia drug.

THE FOURTH EMBODIMENT

Figure 17 depicts yet another embodiment of the present invention. Anesthesia manifold 401 is depicted. As is shown, it includes valves 403, 405, 407 which are "ganged" together in order to form the manifold. Each valve is connected to the main IV line 421 which is a rigid plastic tube. Main IV line 421 includes an inlet 423 and an outlet 425. Saline flows through main IV line 421 from inlet 423 to outlet 425. Each of valves 403, 405, 407 includes a female luer connection 409, 411, 413, each of which includes external threads for mating with the internal threads of a male luer connector associated with a syringe. In this embodiment, each of valves 403, 405, 407 include a rotatable handle 415, 417, 419 which is rotated ninety degrees to move between modes of operation. More specifically, the handle may be rotated to move between a pressure-actuated mode of operation and a mode in which backflow, sampling, aspiration and purging are allowed. In the pressure-actuated mode of operation, a valve element seals the valve to inflow of anesthesia drugs until a sufficient pressure level is obtained. In practice, the pressure is obtained through actuation of the pressure of the plunger relative to the syringe body. Until the pressure is supplied, the valve remains closed. In the aspiration/backflow/sampling/purge mode of operation, the valve allows full bidirectional flow.

THE FIFTH EMBODIMENT

The fifth embodiment of the present invention is depicted in Figure 18. As is shown, anesthesia manifold 501 is provided which combines one stopcock valve with two luer activated valves. More specifically, manifold 501 includes an inlet 503 which receives saline solution from an IV line, and an outlet which provides saline solution

which has been mixed with anesthesia drugs to the patient. The manifold assembly includes a stopcock valve 507, and two luer valves 509, 511. The stopcock valve 507 is conventional, as are the luer-actuatable swabbable type 2 valves 509, 511. The stopcock valve has associated with it a female luer connector 513 which is adapted to releasably connect to a male luer connection associated with a syringe. The stopcock valve 507 further includes a rotatable handle 515 which is utilized to open and close the flowpath to and from female luer 513. When the stopcock valve 507 is open, the anesthesia manifold 501 may be purged, aspirated, connected to another IV line or utilized to draw a sample. When the stopcock valve 507 is closed, the luer activated swabable type 2 valves 509, 511 may be utilized to administer anesthesia drugs via a syringe and have them mixed with the saline solution from the IV line. These luer activated swabable valves are position-sensitive valves which resist flow until a male luer fitting is inserted into luers 509 or 511, thus causing the valve to open, either by depressing a sealing piston or by causing an elastomeric septum to allow passage of fluid (a result which could be caused either by the opening in a slit in the septum or the penetration through the septum of a rigid conduit situated below its surface in the closed position).

THE SIXTH EMBODIMENT

Figures 19 through 27 depict a sixth embodiment of the present invention. Figure 19 is a depiction of the induction valve concept of the sixth embodiment in a pressure-activated position. Figure 20 is a partial one-quarter longitudinal section view of the induction valve of the sixth embodiment in the pressure-activated position. Figure 21 depicts the induction valve of the sixth embodiment in an aspiration/backflow/purge/sample mode of operation. Figure 22 is a partial one-quarter longitudinal section view of the induction valve of the sixth embodiment in the

aspiration/backflow/purge/sample mode of operation. Figure 23 is a depiction of the induction valve of the sixth embodiment in a mode which allows aspiration from the main channel only. Figure 24 is a one-quarter section view of the induction valve of Figure 23 in the aspiration/backflow/purge/sample mode of operation which allows aspiration from the main channel only. Figure 25 is a depiction of the induction valve of the sixth embodiment in the IV gravity feed mode of operation. Figure 26 is a partial one-quarter longitudinal section view of the valve of Figure 25 in the IV gravity feed mode of operation. Figure 27 depicts the induction valve of the sixth embodiment in a "ganged" assembly made up of three valves.

Referring first to Figure 19, valve 611 includes an integrally formed inlet 613 which has integrally formed external threads 614 which allow for the releasable connection to the internal threads of a male luer. Inlet 613 is a female luer which defines the main flow path from an IV line which is connected to an IV bag (neither of which are depicted). Valve 611 further includes outlet 615 which is also integrally formed, and which defines a flow path to the patient. Housing 617 further includes an integrally formed medication inlet 621 which includes integrally formed external threads 623 which define a female luer connection which is suitable for releasable mating with the corresponding threads of a male luer connection which may be found on a syringe or a connection for an IV pump line. Inlet 625 is a central flow passage within the medication inlet 621. It receives medications which are delivered under pressure from either a syringe or an IV pump. Handle 619 is provided to switch valve 611 between the three modes of operation: pressure-activated mode of operation, the aspiration/backflow/purge/sample mode of operation, and the IV gravity feed mode of operation.

Figure 20 is a partial one-quarter longitudinal section view of valve 611 of Figure 19. It is shown in the pressure-activated position. In this condition, handle 619 is aligned with medication inlet 621. An arrow 633 depicts the inward flow of medication. As is shown, the medication acts against seal membrane 631. The pressure of the medication at medication inlet 621 must overcome a predetermined pressure which breaks the seal created by seal member 631 which ordinarily resists the inward flow from medication inlet 621. Once the seal is "broken" medication may flow in the direction of arrow 633 and intermix with saline solution which is provided through inlet 613.

Figure 21 depicts the induction valve of the sixth embodiment in the aspiration/backflow/purge/sample mode of operation. Note that handle 619 is rotated to be in alignment with the inlet 613. In this configuration, the medication inlet 621 may be utilized to aspirate fluid from the patient or to inject medication only (such as medication) into the patient. Figure 22 depicts a partial one-quarter longitudinal section view of the valve 611 of Figure 21. As is shown, medication inlet 621 is no longer sealed by seal membrane 631 and thus is a suitable flow path for aspiration or purging of the valve utilizing a syringe or similar device which connects to medication inlet 621.

Figures 23 and 24 depict an aspiration mode from the main channel only. As is shown in the view of Figure 23, handle 619 is rotated to be in alignment with the outlet 615. Figure 24 is a partial longitudinal section view of the valve of Figure 23 in this particular mode of operation. As is shown in this view, seal membrane 631 is not in sealing contact with medication inlet 621. It is rotated to be out of contact with medication inlet 621. However, the valve body 639 checks the flow path between

inlet 613 and outlet 615. However, the valve body 639 does allow fluid communication between inlet 613 and medication inlet 621. In this manner, medication inlet 621 may be utilized to aspirate from inlet 613, but not from outlet 615.

Figures 25 and 26 depict the IV gravity feed mode of operation. In this mode of operation, handle 619 is rotated to be 180° out of alignment with the medication inlet 621. Figure 26 is a partial one-quarter longitudinal section view of the induction valve of the sixth embodiment of Figure 25. In this configuration, medication inlet 621 is not sealed. Instead, it is open for utilization of an IV pump or gravity-fed infusion. In this mode, fluid enters the valve and intermixes with the saline solution flowing inward through inlet 613. The resulting mixture is passed to the patient through outlet 615.

Figure 27 shows one possible "ganging" of the valves of the sixth embodiment into a manifold which includes three valves.

THE SEVENTH EMBODIMENT

A seventh embodiment of the present invention is depicted in figures 28 through 33. Figure 28 depicts the components which make up the seventh embodiment in exploded view form. Figure 29 is a partial longitudinal section view of a portion of the seventh embodiment. In the view of Figure 29, the valve is depicted in a aspiration/backflow/purge/sample mode of operation. In contrast, Figure 30 is a partial longitudinal section view of a portion of the seventh embodiment; however, Figure 30 depicts the apparatus in a pressure-activated flow mode of operation. Figure 31 is a perspective view of the ring component 705 of Figure 28. Figure 32 is a pictorial

representation of a manifold formed with a number of the valves "ganged" together.

With reference now to Figure 28, the seventh embodiment will now be described. The valve 701 is made up of three major components: a core 703, a ring 705, and a body 707. The core 703 includes a manually-operable portion 709 with outwardly extending "wings" 711, 713 which are adapted to be gripped by thumb and forefinger of an operator. The core may be rotated between two positions, each position corresponds to an operating mode. When the "wings" 711, 713 are aligned as is shown in Figure 29, the valve is in an aspiration/backflow/purge/sample mode of operation. When the "wings" 711, 713 are positioned orthogonal to the position of Figure 29, the valve is in a pressure-activated flow mode of operation. The core 703 further includes a contoured lower portion 716 which is adapted to extend through the central bore of ring 705 and to secure the ring from rotating relatively to the core, with components maintained within the cavity of body 707. Body 707 includes an inlet 715 which is adapted for the receipt of anesthesia drugs or other fluids which are to be administered to a patient, and an outlet 717 which allows flow through the manifold and toward the patient. In the aspiration/backflow/purge/sample mode of operation, fluids may be pulled from the manifold in reverse direction, flowing from outlet 717 toward inlet 715.

With reference now to Figure 29, the aspiration/backflow/purge/sample mode of operation will now be described. In this view, inlet 715 is shown as including an external female connector 719 and a central cavity 721. Outlet 717 includes a central cavity 730. as is shown in this view, flow arrows 723, 725, 727, and 729 depict a possible flow inward through valve 701. In this configuration, fluid may also flow in the reverse direction from outlet 717 to inlet 715. Core 703 is shown as including a

central cavity 731 which aligns with inlet 715 and outlet 717 when the "wing" 711, 713 members of core 703 are aligned with ports 715, 717. In this configuration, the ring 705 of Figure 28 does not interfere with the inward or outward flow of fluid through valve 701. In the view of Figure 29 also depicts the manner by which core 703 is secured in position relative to body 707. More specifically, a circular notch 737 is provided on the exterior surface of core 703 at its distal end. A corresponding shoulder 739 is formed in the central cavity of body 707 and adapted in size and location in order to mate with circular notch 737.

Figure 30 depicts the valve 701 in a pressure-activated flow mode of operation. In this configuration, ring 705 operates to permit the flow of fluid in one direction only and to check the flow of fluid in the opposite direction. In the view of Figure 30, flow arrows 751, 753, 755, 757, 759, 761, and 763 depict the flow of fluid through valve 701 in this particular mode of operation. As is shown, ring 705 includes flap members 771, 773, which extend downward into the flowpath when the core 703 is rotated to change the mode of operation. Flaps 771, 773, are adapted to move easily in response to one flow direction, but to oppose flow in the opposite direction. For example, flap 773 is adapted to be in close physical proximity to flow channel 721 of inlet 715. Fluid flowing inward through inlet 715 will push flap 773 radially inward and will flow under and around flap 773. In the event of backflow, flap 773 will be pushed into sealing engagement with cavity 721, thus checking backflow. Likewise, flap 771 is in close physical proximity to cavity 731 of core 703. Flap 771 will move radially outward in response to flow moving from inlet 715 to outlet 717. Fluid will urge flap 771 radially outward and will flow around flap 771. However, flap 771 will check the reverse flow by sealing engagement of flap 771 to cavity 731 of core 703. Note that there is an asymmetry 773 and 771. This asymmetry facilitates the

operation of the valve during the pressure activated flow mode. In alternative embodiments, it may be possible to utilize only a single flap. In such an alternative, flap 771 is likely excluded and flap 773 is utilized solely to preferentially direct the flow of fluid inward in response to the pressure from fluid at inlet 715, but to check the flow of fluid backward through valve 701.

Figure 31 depicts ring 705 in a perspective view. As is shown, a shoulder 781 is provided at the upper end of ring 705 to engage body 707. Cavities 783, 785 are provided to allow fluid to pass through ring 705 during the aspiration/backflow/purge/sample mode of operation. Cavities 787, 789 are provided at the lower portion of ring 705 in order to define the flap members 711, 713.

Figure 32 is a pictorial representation of an anesthesia manifold formed through the "ganging" together of valves 714, 716, 718. The manifold 710 includes a central flow member 712 which is mechanically coupled to the outlet members of valves 714, 716, 718. The inlet members 720, 722, 724 are adapted to mate with syringes or medication pumps in order to supply medication and/or fluids to the manifold 710. In this view, the wings of the valve members are shown as being aligned with the inlet ports so these valves are in the aspiration/backflow/purge/sample mode of operation.

Figure 33 is a pictorial representation of an anti-rotational interlock feature 801 of this particular embodiment. As is shown, the core 703 is disposed within a central cavity defined within ring 705. Ring 705 is disposed within a central cavity of body 707. As is shown, ribs 790, 792 are formed on the exterior surface of core 703. They extend along at least a substantial portion of the outer surface of core 703. Corresponding

slots 794, 796 are defined within the central bore of ring 705. The ribs 790, 792 are adapted in size and shape in order to fit within slot 794, 796. In alternative embodiments, as few as one rib and slot may be utilized to lock the core 703 to ring 705 forcing them to move together as the core is rotated relative to body 707. In yet alternative embodiments, a plurality of ribs and slots may be provided between core 703 and ring 705. In an alternative configuration, the ribs may be provided on ring 705 and the slots may be provided on core 703. This anti-rotational interlock feature 801 ensures that the core 703 and ring 705 are always properly aligned.

Although the invention has been described with reference to a particular embodiment, this description is not meant to be construed in a limiting sense. Various modifications of the disclosed embodiments as well as alternative embodiments of the invention will become apparent to persons skilled in the art upon reference to the description of the invention. It is therefore contemplated that the appended claims will cover any such modifications or embodiments that fall within the scope of the invention.